

Subpart B—Biological Defense Safety Policy and Procedures

§ 626.5 Policy.

(a) This regulation applies to BDP RDTE operations involving etiologic agents being investigated by DA for biological defense purposes.

(b) Specific biological safety requirements and guidance are contained in DA Pam 385–69.

§ 626.6 Mishap reporting and investigation.

Biological defense RDTE related mishaps will be reported and investigated per AR 385–40 and AR 40–400. Med 16 Report will be used to report only personnel exposure or illness related to the BDP.

§ 626.7 Administrative and work practice controls.

(a) The cardinal principle for safety in BDP operations is to minimize the potential exposure of personnel to etiologic agents. In practice, this means conducting RDTE activities using the appropriate facilities, equipment, and procedures for the biosafety level (BL), and requiring only the minimum number of appropriately trained personnel, the minimum period of time, and minimum amount of the material, consistent with program objectives and safe operations.

(b) Open air testing under the BDP is restricted to use of simulants only, unless the Secretary of Defense determines that testing is necessary for national security in accordance with section 409, Public Law 91–121, 83 Stat. 204, signed November 18, 1967. Also, for RDTE involving protective equipment or detection devices, the least hazardous etiologic agent consistent with mission objectives will be employed. All testing of such equipment employing etiologic agents will be in appropriate biosafety level containment laboratories.

(c) A hazard analysis, to determine safety precautions, necessary personnel protection and engineering features, and procedures to prevent exposure, will be completed for—

(1) All BDP operations involving etiologic agents.

(2) A change in process or control measures that may increase potential contact or concentrations of biological material.

(d) An SOP is required for all biological defense RDTE operations. The SOP will—

(1) Describe in detail all necessary operational and safety requirements.

(2) Describe in detail actions to take in the event of mishap.

(3) Describe in detail the location of required emergency response equipment.

(4) Be available at the work site.

(5) Forbid concurrent unrelated work during biological defense RDTE operations within a laboratory area or suite.

(6) Be approved by the commander or the safety officer and signed by workers involved in the operation.

(7) Provide names and telephone numbers of responsible personnel.

(e) Training and information. All personnel who work directly with etiologic agents in the BDP, or who otherwise have a potential for exposure, will receive appropriate training to enable them to work safely and to understand the relative significance of agent exposures.

(1) This training will include signs and symptoms of etiologic agent exposure, information on sources of exposure, possible adverse health affects, and practices and controls used to limit exposures. The environmental and medical monitoring procedures in use, their purposes, worker responsibilities in health protection programs, and handling of laboratory mishaps will also be presented.

(2) Workers will be required to demonstrate proficiency before performing potentially hazardous operations. Refresher training will be repeated at least annually.

(3) Initial and refresher training will be documented and kept on file as a permanent record.

(f) Medical surveillance. A medical surveillance program (see AR 40–5) will be established for all personnel (military and civilian) who may be potentially exposed to etiologic agents.